DEPARTMENT OF COMMUNITY HEALTH
DIRECTOR'S OFFICE

BUREAU OF HEALTH SYSTEMS - RADIATION SAFETY SECTION

IONIZING RADIATION RULES
PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

Filed with the Secretary of State on _____
These rules take effect 7 days after filing with the Secretary of State

(By authority conferred on the director of the department of community health by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, and 2003-01, MCL 330.3101, 445.2001, and 445.2011)

R 325.5701, R 325.5703, R 325.5705, R 325.5707, R 325.5709, R 325.5711, R 325.5713, R 325.5715, R 325.5717, R 325.5719, and R 325.5721 of the Michigan Administrative Code are added as follows:

R 325.5701 Purpose and scope.
Rule 701. (1) This part establishes requirements governing the use of computed tomography (CT) scanners in the healing arts.
(2) This part applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.
(3) A CT scanner is exempt from this part if the scanner meets 1 of the following:
(a) Generates a peak power of 5 kilowatts or less as certified by the manufacturer.
(b) Is used only for attenuation corrections and anatomical markers as part of a positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) study.
(c) Is used as a simulator solely for treatment planning purposes in conjunction with a megavoltage radiation therapy unit.
(d) Is used for intra-operative guidance tomography.
(4) In addition to the requirements of this part, all registrants are subject to R 325.5001 to R 325.5665.

R 325.5703 Definitions.
Rule 703. (1) As used in this part the definitions in 21 C.F.R. 1020.33, "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.
(2) As used in this part the following definitions apply:

(a) "Annual" means a period of 12 consecutive months.

(b) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms.

(c) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT scanner hybrids if used for CT only procedures.

(d) "Medical physicist" means a person trained in evaluating the performance of CT scanners, related equipment, and facility quality assurance programs and who meets the requirements in R 325.5707.

(e) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce three-dimensional images of functional processes in the body.

(f) "Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in R 325.5705.

(g) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce a tomogram.

(h) "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

(i) "Traceable to a national standard" means an instrument is calibrated at either the national institute of standards and technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3% of the national standard in the appropriate energy range.

R 325.5705 Radiologic technologists.

Rule 705. All CT examinations shall be performed by a radiologic technologist who meets the requirements of subdivisions (a) and (b) of this rule or by a physician or osteopathic physician licensed under article 15 of the act.

(a) Initial qualifications. Before beginning to perform CT examinations independently, a technologist shall meet both of the following:

(i) Be currently registered by the American registry of radiologic technologists (ARRT).

(ii) Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection or have the advanced certification in computed tomography from the ARRT.

(b) Continuing education. A technologist shall be in compliance with the ARRT requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to computed tomography.

R 325.5707 Medical physicist.

Rule 707. Each registrant with 1 or more CT scanners shall employ or contract with a medical physicist to review the quality and safety of the operation of the CT scanner. The medical physicist shall meet all of the following:

(a) Initial qualifications. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet 1 of the following:

(i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology, or in diagnostic imaging physics by the American board of medical physics, or in diagnostic radiology physics or by the Canadian college of physicists in medicine.

(ii) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment.

(iii) During the 3 years immediately following the effective date of this part, a medical physicist that does not meet the requirements of paragraph (i) or (ii) of this subdivision shall be considered qualified if the physicist conducted evaluations of at least 3 CT scanners between January 1, 2007 and January 1, 2010. Three years after the effective date of this part, a medical physicist shall meet the requirements of paragraph (i) or (ii) of this subdivision.

(b) Continuing experience. After the second anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT units in the prior 24-month period.

(c) Continuing education. After the third anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units in CT, at least half shall be category 1, in the prior 36-month period.

(d) Reestablishing Qualifications. A medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(i) A medical physicist who fails to meet the continuing experience requirements of subdivision (b) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist, to meet the requirements of subdivision (b) of this rule.

(ii) A medical physicist who fails to meet the continuing education requirements of subdivision (c) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (c) of this rule.

R 325.5709 Record retention for personnel.

Rule 709. CT facilities shall maintain records to document the qualifications of all personnel who worked at the facility as a radiologic technologist or medical physicist. These records shall be available for review by the department. Records of personnel no longer employed by the CT facility shall be kept on file until the next inspection

following the employee's termination has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.

R 325.5711 Equipment requirements.

Rule 711. (1) The regulations in 21 C.F.R. 1020.33(c), (d), (f), (g), (h), (i), and (j), "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(2) CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.

R 325.5713 Enclosures

Rule 713. A CT equipment enclosure shall be in compliance with the requirements of R 325.5331 excluding subrule (7) of the rule.

R 325.5715 Conditions of operation

Rule 715. (1) Operation of a CT scanner shall comply with the requirements of R 325.5333.

(2) The CT scanner shall be operated from a shielded position behind a primary protective barrier pursuant to R 325.5331(5).

(3) Scanning protocols shall be established by an authorized interpreting physician or the medical physicist.

(4) The CT radiologic technologist or physician operator shall check the display panel before performing each scan to make sure the amount of radiation to be delivered is appropriate for the technique and individual patient and after performing each scan to determine if the amount of radiation delivered was appropriate. Doses in excess of expected values shall be documented and reviewed by an interpreting physician or medical physicist.

R 325.5717 Quality control program.

Rule 717. (1) A quality control program shall be established and implemented under the supervision of the medical physicist. The program shall include testing that addresses clinical image quality, patient radiation dose, personnel radiation protection, and compliance with the provisions of this part.

(2) Initial performance testing of the CT system shall be completed by the medical physicist before use on human patients.

(3) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. The dosimetry system shall have been calibrated within the preceding 24 months and the calibration shall be traceable to a national standard as specified in R 325.5703(2)(i).

(4) Quality control tests shall be performed following written procedures and methods. If the results of a quality control test fall outside the control limits, corrective

action shall be taken and documented according to instructions provided by the medical physicist.

R 325.5719 Annual medical physicist evaluation.

Rule 719. (1) The performance of each CT machine shall be evaluated by the medical physicist at least annually. This evaluation should include the following:

(a) Alignment light accuracy.
(b) Alignment of table to gantry.
(c) Table and gantry tilt.
(d) Slice localization from scanned projection radiograph.
(e) Table increment accuracy.
(f) Slice thickness.
(g) Image quality, including the following:
(i) High-contrast resolution.
(ii) Low-contrast resolution.
(iii) Image uniformity.
(iv) Noise.
(v) Artifact evaluation.
(h) CT number accuracy and linearity.
(i) Dosimetry, including the following:
(i) Dose indicator such as computed tomography dose index (CTDI).
(ii) Patient radiation dose for representative examinations.
(j) Safety evaluation, including the following:
(i) Visual inspection.
(ii) Audible and visual signals.
(iii) Posting requirements.
(iv) Scattered radiation measurements.
(k) Review of the ongoing quality control program.

(2) The medical physicist shall prepare a report that includes a summary of this evaluation and recommendations for necessary improvements. The report shall include the type and date of the last calibration of the dosimetry system used.

(3) The medical physicist shall send the report to the CT facility within 30 days of the date of the evaluation and the facility shall maintain the report for a period of at least 5 years. Copies of the report shall be available for review by the department.

R 325.5721 Ongoing quality control.

Rule 721. (1) A medical physicist shall establish an ongoing quality control program for the CT facility. The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The quality control tests shall be performed by this technologist or by other personnel qualified to perform the tests following written procedures and methods under R 325.5717(4).

(2) The ongoing quality control testing should include the following:

(a) Image quality, including the following:
(i) High-contrast resolution.
(ii) Low-contrast resolution.

(iii) Image uniformity.
(iv) Noise.
(v) Artifact evaluation.
(b) Alignment light accuracy.
(c) Slice thickness.
(d) CT number accuracy.
(e) Dose display devices.
(3) Records of the results from the ongoing quality control program shall be maintained on file at the CT facility for at least 2 years. These records shall be available for review by the department.